K131975

510(k) Summary

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006	
	Contact: HKatz@AlfaWassermannUS.com Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	OCT 0 2 2013
Date Summary Prepared:	September 26, 2013	
Device:	Trade Name:	ACE Direct Total Iron-Binding Capacity (TIBC) Reagent
	Classification:	Class 1
	Common/Classification Name:	Direct Total Iron-Binding Capacity (TIBC) (21 C.F.R. § 862.1415) Product Code JMO
	Trade Name:	ACE Total Iron Reagent
	Classification:	Class 1
	Common/Classification Name:	Photometric Method, Iron (Non-Heme) (21 C.F.R. § 862.1410) Product Code JIY
	Trade Name:	ACE LDH-L Reagent
	Classification:	Class 2
	Common/Classification Name:	NAD Reduction/NADH Oxidation, Lactate Dehydrogenase (21 C. F.R. § 862.1440) Product Code CFJ

Predicate Devices:	Manufacturer for reagent system predicates: Alfa Wassermann ACE Clinical Chemistry System and ACE Reagents (K930104, K944911, K931786)
Device Descriptions:	In the ACE Direct Total Iron-Binding Capacity (TIBC) Reagent assay, Direct TIBC Color Reagent, an acidic buffer containing an iron-binding dye and ferric chloride, is added to the serum sample. The low pH of Direct TIBC Color Reagent releases iron from transferrin. The iron then forms a colored complex with the dye. The colored complex at the end of the first step represents both the serum iron and excess iron already present in Direct TIBC Color Reagent. Direct TIBC Buffer, a neutral buffer, is then added, shifting the pH and resulting in a large increase in the affinity of transferrin for iron. The serum transferrin rapidly binds the iron by abstracting it from the dye-iron complex. The observed decrease in absorbance of the colored dye-iron complex is directly proportional to the total iron-binding capacity of the serum sample. The absorbance is measured at 647 nm. In the ACE Total Iron Reagent assay, transferrin-bound iron in serum is released at an acidic pH and reduced from ferric to ferrous ions. These ions react with ferrozine to form a violet colored complex, which is measured bichromatically at 554 nm/692 nm. The intensity of color produced is directly proportional to the serum iron concentration. In the ACE LDH-L Reagent assay, lactate dehydrogenase catalyzes the conversion of L-lactate to pyruvate. Nicotinamide adenine dinucleotide (NAD^+) acts as an acceptor for the hydrogen ions released from the L-lactate and is converted to reduced nicotinamide adenine dinucleotide (NADH). NADH absorbs strongly at 340 nm whereas NAD^+ does not. Therefore, the rate of conversion of NAD^+ to NADH can be determined by monitoring the increase in absorbance bichromatically at 340 nm/647 nm. This rate of conversion from NAD+ to NADH is directly proportional to the lactate dehydrogenase activity in the sample.

Intended Use:	Indications for Use: The ACE Direct Total Iron-Binding (TIBC) Reagent is intended for the quantitative determination of total iron-binding capacity in serum using the ACE Alera Clinical Chemistry System. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE Total Iron Reagent is intended for the quantitative determination of iron in serum using the ACE Alera Clinical Chemistry System. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE LDH-L Reagent is intended for the quantitative determination of lactate dehydrogenase activity in serum using the ACE Alera Clinical Chemistry System. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction and tumors of the lung or kidneys. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.
Technological Characteristics:	The ACE Direct Total Iron-Binding Capacity (TIBC) Reagent is composed of two reagent bottles (Direct TIBC Color Reagent and Direct TIBC Buffer). The Direct TIBC Color Reagent (R1) contains: Chromazurol B, Cetrimide, ferric chloride and acetate buffer. The Direct TIBC Buffer (R2) contains: sodium bicarbonate buffer. The ACE Total Iron Reagent is composed of two reagent bottles (Buffer and Color Reagent). The Buffer (R1) contains: hydroxylamine hydrochloride, acetate buffer (pH 4.5) and surfactant. The Color Reagent (R2) contains: ferrozine and hydroxylamine hydrochloride. The ACE LDH-L Reagent is composed of two reagent bottles (Substrate and Coenzyme Reagent). The reagents contain L-lactic acid and nicotinamide adenine dinucleotide.

Device Comparison with Predicate

Comparison of similarities and differences with predicate device

ACE Direct Total Iron-Binding Capacity (TIBC) Reagent

ACE Direct TIBC Reagent	Candidate Device	Predicate Device k930104 (ACE Direct TIBC Reagent)
Intended Use/ Indications for Use	The ACE Direct Total Iron-Binding Capacity (TIBC) Reagent is intended for the quantitative determination of total iron-binding capacity in serum using the **ACE *Alera* Clinical Chemistry System**. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. This test is intended for use in **clinical laboratories and physician office laboratories**. For *in vitro* diagnostic use only.	The ACE Direct Total Iron-Binding Capacity (TIBC) Reagent is intended for the quantitative determination of total iron-binding capacity in serum using the ACE Clinical Chemistry System. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. This test is intended for use in clinical laboratories. For *in vitro* diagnostic use only.
Method	Photometric	Same
Calibration Stability	30 days	Same
On Board Stability	30 days	Same
Sample Type	Serum	Same
Sample Volume	16 µL	Same
Reaction Volume	291 µL	Same
Expected values	250-425 µg/dL	250-450 µg/dL
Measuring range	52-700 µg/dL	From the lowest calibrator concentration to 700 µg/dL
Sample Stability	Separated from cells, serum TIBC is stable for 4 days at 18-26°C and 1 week at 2-8°C.	Same

ACE Total Iron Reagent

ACE Total Iron Reagent	Candidate Device	Predicate Device k944911 (ACE Total Iron Reagent)
Intended Use/Indications for Use	The ACE Total Iron Reagent is intended for the quantitative determination of iron in serum using the **ACE *Alera* Clinical Chemistry System.** Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. This test is intended for use in **clinical laboratories and physician office laboratories**. For *in vitro* diagnostic use only.	The ACE Total Iron Reagent is intended for the quantitative determination of iron in serum using the ACE Clinical Chemistry System. Iron (non-heme) measurements are used in the diagnosis and treatment of diseases such as iron deficiency anemia, hemochromatosis (a disease associated with widespread deposit in the tissues of two iron-containing pigments, hemosiderin and hemofuscin, and characterized by pigmentation of the skin), and chronic renal disease. This test is intended for use in clinical laboratories. For *in vitro* diagnostic use only.
Method	Photometric	Same
Calibration Stability	30 days	Same
On Board Stability	30 days	Same
Sample Type	Serum	Same
Sample Volume	50 µL	Same
Reaction Volume	335 µL	Same
Expected values	Male: 65-175 µg/dL Female: 50-170 µg/dL	Same
Measuring range	9.15-600 µg/dL	2-600 µg/dL
Sample Stability	Separated from cells, serum iron is stable for 7 days at room temperature (20-25°C), 3 weeks at 4-8°C and up to 1 year at -20°C.	Separated from cells, serum iron is stable for 4 days at room temperature (15-30°C) and 7 days at 2-8°C.

ACE LDH-L Reagent

ACE LDH-L Reagent	Candidate Device	Predicate Device k931786 (ACE LDH-L Reagent)
Intended Use/Indications for Use	The ACE LDH-L Reagent is intended for the quantitative determination of lactate dehydrogenase activity in serum using the **ACE *Alera* Clinical Chemistry System**. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction and tumors of the lung or kidneys. This test is intended for use in **clinical laboratories and physician office laboratories**. For *in vitro* diagnostic use only.	The ACE LDH-L Reagent is intended for the quantitative determination of lactate dehydrogenase activity in serum using the ACE Clinical Chemistry System. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction and tumors of the lung or kidneys. This test is intended for use in clinical laboratories. For *in vitro* diagnostic use only.
Method	Photometric	Same
Calibration Stability	Not a calibrated test	Same
On Board Stability	30 days	Same
Sample Type	Serum	Same
Sample Volume	5 µL	Same
Reaction Volume	170 µL	Same
Expected values	100-190 U/L	Same
Measuring range	18-850 U/L	17-850 U/L
Sample Stability	Separated from cells, LDH activity is stable for 7 days at 20-25°C, 4 days at 4-8°C and 6 weeks at -20°C. Loss of activity after freezing has also been noted.	Separated from cells, LDH activity is stable for 3 days at both 2-8°C and room temperature. Loss of activity after freezing has also been noted.

Performance Data:

Reportable Range

Performance data for the Alfa Wassermann ACE Reagents on the Alfa Wassermann ACE *Alera* Clinical Chemistry System

Detection Limits - ACE *Alera* Clinical Chemistry System

	TIBC	Iron	LDH-L
LoB	11 µg/dL	0 µg/dL	11 U/L
LoD	24 µg/dL	1 µg/dL	18 U/L
LoQ	52 µg/dL	9.15 µg/dL	18 U/L

Linearity - ACE *Alera* Clinical Chemistry System

Reagent	Low Level Tested	High Level Tested	Linear to:	Linear Regression equation
TIBC	34 µg/dL	740 µg/dL	700 µg/dL	$y = 1.020x + 3.1$ $r^2 = 0.9981$
Iron	6 µg/dL	666 µg/dL	600 µg/dL	$y = 1.030x + 1.9$ $r^2 = 0.9986$
LDH-L	8 U/L	895 U/L	850 U/L	$y = 1.050x - 0.7$ $r^2 = 0.9981$

Performance Data:

Interferences

Interferences - ACE *Alera* Clinical Chemistry System

Interferent	No Significant Interference at or below:		
	TIBC	Iron	LDH-L
Icterus	59 mg/dL	59 mg/dL	50 mg/dL
Hemolysis	188 mg/dL*	125 mg/dL*	<31 mg/dL*
Lipemia	1000 mg/dL	125 mg/dL	1000 mg/dL
Ascorbic Acid	3 mg/dL	6 mg/dL	6 mg/dL

* Do not use hemolyzed samples.

Performance Data:

Precision – In-House

Precision - ACE *Alera* Clinical Chemistry System

ACE *Alera*		Precision (SD, %CV)		
		Mean	Within-Run	Total
TIBC µg/dL	Low	217	4.1, 1.9%	6.7, 3.1%
	Mid	270	3.7, 1.4%	7.1, 2.6%
	High	310	5.0, 1.6%	8.6, 2.8%
Iron µg/dL	Low	62	3.2, 5.2%	4.6, 7.3%
	Mid	145	2.2, 1.5%	4.2, 2.9%
	High	226	4.1, 1.8%	5.0, 2.2%
LDH-L U/L	1	77	3.8, 4.9%	4.2, 5.5%
	2	119	5.1, 4.3%	5.2, 4.3%
	3	270	4.5, 1.7%	5.8, 2.1%
	4	651	12.6, 1.9%	13.5, 2.1%

Performance Data:

Method Comparison – In-House

Method Comparison - ACE *Alera* Clinical Chemistry System

In-House ACE (x) vs. In-House ACE *Alera* (y)

	TIBC	Iron	LDH-L
n	50	48	58
Range	59 to 676 µg/dL	13 to 549 µg/dL	20 to 799 U/L
Slope	0.987	0.993	0.997
Intercept	3.6	0.9	-3.6
Correlation Coefficient	0.9960	0.9995	0.9991
Std. Error	9.2	3.6	6.8
CI Slope	0.962 to 1.013	0.984 to 1.003	0.985 to 1.008
CI Intercept	-7.2 to 14.4	-0.6 to 2.3	-6.1 to -1.1

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

Direct TIBC n=20		ACE Result			ACE *Alera* Result		
			µg/dL SD, %CV			µg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	336	2.9	5.5	330	5.1	5.8
			0.9%	1.6%		1.5%	1.8%
POL 1	1	290	10.8	15.6	284	8.3	9.6
			3.7%	5.4%		2.9%	3.4%
POL 2	1	275	3.5	11.4	259	5.6	8.5
			1.3%	4.1%		2.2%	3.3%
POL 3	1	295	5.4	5.5	276	9.1	16.7
			1.8%	1.9%		3.3%	6.0%
In-House	2	455	5.0	8.1	450	4.9	6.8
			1.1%	1.8%		1.1%	1.5%
POL 1	2	452	10.2	10.4	464	6.3	6.6
			2.3%	2.3%		1.4%	1.4%
POL 2	2	442	5.9	12.5	444	4.2	5.4
			1.3%	2.8%		1.0%	1.2%
POL 3	2	465	4.7	5.3	453	3.2	15.5
			1.0%	1.1%		0.7%	3.4%
In-House	3	539	9.8	12.8	530	9.4	10.8
			1.8%	2.4%		1.8%	2.0%
POL 1	3	531	17.1	20.4	544	8.2	8.3
			3.2%	3.8%		1.5%	1.5%
POL 2	3	530	7.4	14.1	520	5.0	9.0
			1.4%	2.7%		1.0%	1.7%
POL 3	3	551	4.6	5.9	533	12.6	20.2
			0.8%	1.1%		2.4%	3.8%

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

Total Iron n=20		ACE Result			ACE *Alera* Result		
			µg/dL SD, %CV			µg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	117	1.4	2.6	119	1.8	2.5
			1.2%	2.2%		1.5%	2.1%
POL 1	1	120	6.4	6.9	119	2.7	3.2
			5.4%	5.8%		2.3%	2.7%
POL 2	1	120	6.3	6.6	122	3.1	3.1
			5.3%	5.5%		2.6%	2.6%
POL 3	1	121	4.4	4.4	116	3.2	3.4
			3.7%	3.7%		2.8%	3.0%
In-House	2	223	2.9	5.6	222	3.8	5.1
			1.3%	2.5%		1.7%	2.3%
POL 1	2	227	3.4	3.9	229	2.0	2.5
			1.5%	1.7%		0.9%	1.1%
POL 2	2	227	2.6	5.1	235	2.3	2.4
			1.1%	2.2%		1.0%	1.0%
POL 3	2	225	1.3	1.9	229	3.4	3.9
			0.6%	0.8%		1.5%	1.7%
In-House	3	416	8.7	9.1	412	5.2	5.7
			2.1%	2.2%		1.3%	1.4%
POL 1	3	420	5.0	5.6	424	4.0	4.6
			1.2%	1.3%		0.9%	1.1%
POL 2	3	423	6.6	9.3	435	2.4	5.3
			1.6%	2.2%		0.5%	1.2%
POL 3	3	422	5.6	6.0	428	11.1	11.1
			1.3%	1.4%		2.6%	2.6%

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

LDH-L n=20		ACE Result			ACE *Alera* Result		
			U/L SD, %CV			U/L SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	121	2.8	4.3	118	2.9	5.7
			2.3%	3.6%		2.4%	4.8%
POL 1	1	113	2.1	5.4	116	1.7	4.9
			1.9%	4.8%		1.5%	4.3%
POL 2	1	114	2.5	6.4	118	3.0	5.1
			2.2%	5.6%		2.5%	4.3%
POL 3	1	117	2.1	2.7	124	3.4	4.7
			1.8%	2.3%		2.7%	3.8%
In-House	2	446	5.8	6.9	433	4.7	6.5
			1.3%	1.5%		1.1%	1.5%
POL 1	2	433	5.8	8.1	437	2.9	5.8
			1.3%	1.9%		0.7%	1.3%
POL 2	2	433	4.8	5.7	449	3.7	5.2
			1.1%	1.3%		0.8%	1.2%
POL 3	2	437	4.5	5.2	446	5.8	6.6
			1.0%	1.2%		1.3%	1.5%
In-House	3	715	10.1	11.9	699	5.3	8.5
			1.4%	1.7%		0.8%	1.2%
POL 1	3	699	10.0	18.0	698	8.6	11.5
			1.4%	2.6%		1.2%	1.6%
POL 2	3	698	12.7	12.7	726	5.4	10.0
			1.8%	1.8%		0.8%	1.4%
POL 3	3	697	7.6	8.8	716	14.3	16.9
			1.1%	1.3%		2.0%	2.4%

Performance Data:

Method Comparison - POL on ACE

POL – Method Comparison for ACE Clinical Chemistry System

Reagent	Statistic	In-House (x) vs. ACE POL 1 (y)	In-House (x) vs. ACE POL 2 (y)	In-House (x) vs. ACE POL 3 (y)
TIBC	n	50	50	50
	Range	59 to 676	59 to 676	59 to 676
	Regression	y = 0.979x + 4.3	y = 0.974x + 8.7	y = 1.006x – 1.4
	Correlation	0.9972	0.9966	0.9966
	Std. Error Est.	7.7	8.4	8.7
	CI Slope	0.958 to 1.000	0.951 to 0.998	0.982 to 1.030
	CI Intercept	-4.8 to 13.3	-1.2 to 18.5	-11.6 to 8.8
Iron	n	48	48	48
	Range	13 to 549	13 to 549	13 to 549
	Regression	y = 0.977x – 1.3	y = 0.992x – 0.8	y = 0.992x + 0.9
	Correlation	0.9990	0.9994	0.9994
	Std. Error Est.	5.0	3.8	3.8
	CI Slope	0.964 to 0.990	0.982 to 1.003	0.982 to 1.002
	CI Intercept	-3.3 to 0.6	-2.3 to 0.7	-0.6 to 2.4
LDH-L	n	51	51	51
	Range	74 to 799	74 to 799	74 to 799
	Regression	y = 0.996x + 1.3	y = 1.010x – 5.3	y = 0.978x + 7.2
	Correlation	0.9979	0.9989	0.9989
	Std. Error Est.	10.6	7.7	7.6
	CI Slope	0.978 to 1.014	0.996 to 1.023	0.964 to 0.991
	CI Intercept	-3.0 to 5.6	-8.5 to -2.2	4.2 to 10.3

Performance Data:

Method Comparison - POL on ACE *Alera*

POL – Method Comparison for ACE *Alera* Clinical Chemistry System

Reagent	Statistic	In-House (x) vs. ACE *Alera* POL 1 (y)	In-House (x) vs. ACE *Alera* POL 2 (y)	In-House (x) vs. ACE *Alera* POL 3 (y)
TIBC	n	50	50	50
	Range	59 to 676	59 to 676	59 to 676
	Regression	y = 0.994x + 12.4	y = 0.973x + 0.1	y = 1.005x + 9.0
	Correlation	0.9934	0.9954	0.9898
	Std. Error Est.	12.0	9.8	15.1
	CI Slope	0.961 to 1.027	0.946 to 1.001	0.963 to 1.047
	CI Intercept	-1.7 to 26.5	-11.4 to 11.6	-8.7 to 26.6
Iron	n	48	48	48
	Range	13 to 549	13 to 549	13 to 549
	Regression	y = 0.976x + 1.0	y = 0.976x + 2.3	y = 0.951x + 0.8
	Correlation	0.9986	0.9981	0.9966
	Std. Error Est.	5.9	6.8	8.9
	CI Slope	0.960 to 0.991	0.959 to 0.994	0.927 to 0.974
	CI Intercept	-1.4 to 3.3	-0.4 to 5.0	-2.7 to 4.4
LDH-L	n	51	51	51
	Range	74 to 799	74 to 799	74 to 799
	Regression	y = 0.992x + 3.5	y = 1.027x + 3.4	y = 1.010x + 2.5
	Correlation	0.9986	0.9989	0.9984
	Std. Error Est.	8.8	8.1	9.3
	CI Slope	0.977 to 1.008	1.013 to 1.041	0.994 to 1.026
	CI Intercept	-0.1 to 7.1	0.2 to 6.7	-1.3 to 6.2

Conclusions:

Based on the foregoing data, the device is safe and effective for use in clinical laboratories and physician office laboratories. These data indicate that the ACE *Alera* Clinical Chemistry System is substantially equivalent to the predicate device ACE Clinical Chemistry System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 2, 2013

Alfa Wassermann Diagnostic Technologies, LLC
c/o Hyman Katz, Ph.D.
4 Henderson Drive
WEST CALDWELL NJ 07006

Re: K131975
Trade/Device Name: ACE LDH-L Reagent
ACE Direct Total Iron-Binding Capacity (TIBC) Reagent
ACE Total Iron Reagent
Regulation Number: 21 CFR 862.1440
Regulation Name: Lactate dehydrogenase test system
Regulatory Class: II, exempt, meets limitations of exemption per 21 CFR 862.9 (c)(9)
Product Code: CFJ, JMO, JIY
Dated: August 30, 2013
Received: September 4, 2013

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number : k131975

Device Name: ACE Direct Total Iron-Binding Capacity (TIBC) Reagent

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Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Devices or Radiological Health
510(k) k131975

Indications for Use

510(k) Number : k131975

Device Name: ACE LDH-L Reagent

Indications for Use: The ACE LDH-L Reagent is intended for the quantitative determination of lactate dehydrogenase activity in serum using the ACE Alera Clinical Chemistry System. Lactate dehydrogenase measurements are used in the diagnosis and treatment of liver diseases such as acute viral hepatitis, cirrhosis, and metastatic carcinoma of the liver, cardiac diseases such as myocardial infarction and tumors of the lung or kidneys. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21.CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

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